

**B | BRAUN**

**CONFIDENTIAL**

B. Braun Medical Inc.  
824 Twelfth Avenue  
PO Box 4027  
Bethlehem, PA 18018-0027  
Telephone: 610-691-5400  
Telefax: 610-691-2202

May 9, 1996

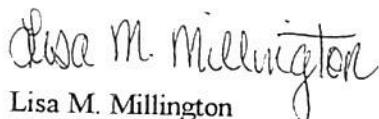
Mr. Daniel E. Lucero, Env. Eng.  
US EPA Region III (3AT12)  
841 Chestnut Building  
Philadelphia, PA 19107

Dear Mr. Lucero,

Enclosed please find B. Braun Medical's Initial Notification Report per the EtO MACT codified under 40 C.F.R. Part 63, Supart O. Included with the Initial Notification Report please find Attachment 1--B. Braun Medical's test plan of the DEOXX Emissions Control Units; Attachment 2--1995 Test Results from B. Braun Medical's DEOXX System; Addendum to Attachment 2--modified calculations to the 1995 Test Results; and Attachment 3--1994 Form R.

If you have any questions or concerns regarding this matter, please do not hesitate to contact me at anytime.

Sincerely,

  
Lisa M. Millington

cc: T. Ronca  
A. Kingston  
D. Calek  
S. Stancick



**CONFIDENTIAL**

Date: May 6, 1996

**Example 2**

Initial Notification Report

Applicable rule: Subpart O--National Emission Standards for EO Commercial Sterilization and Fumigation Operations

Effective date:<sup>1</sup> December 8, 1994

All facilities using 1 ton or more of ethylene oxide (EO) per year are required to submit this notification. See section 63.366 of subpart O and section 63.9 of subpart A.

The initial notification should be submitted to the appropriate authority within 120 days after the effective date (120 days after the effective date is April 8, 1995) or within 120 days after initial startup, whichever is later.

1. Print or type the following for each plant in which EO commercial sterilization and fumigation operations are performed:

Name of Owner/Operator B. Braun Medical, Inc.

Mailing Address 824 12th Avenue

City Bethlehem State PA Zip Code 18018

Plant Name B. Braun medical, Inc.

Plant Address (if different than owner/operator's)

Street Address 901 Postal Road

City Allentown State PA Zip Code 18103

Phone Number (610) 266-0500

Plant Contact/Title Steve Stancick, Sterilization Manager

The only EO commercial sterilization and fumigation operations that are exempt from subpart O are those used for research and laboratory purposes (see section 112(c)(7) of the Clean Air Act).

2. Note the initial startup date for the source: May 17, 1987  
Month/day/yr

<sup>1</sup>The date of promulgation in the Federal Register.

Plant Name: B. Braun Medical, Inc.

3. Check the boxes that apply; note the compliance data.<sup>2</sup>

Compliance Date

- ☒ Initial startup occurred on or before December 8, 1997.

December 8, 1997

- ☐ Initial startup occurred after December 8, 1997.

(compliance date =  
initial startup date)

- ☒ The facility uses 10 tons of EO or more per year.

- ☐ The facility uses 1 to 10 tons of EO per year.

4. Complete the following table for each vent type (i.e., sterilization chamber or aeration room). If additional space is needed, make copies of this page. The first row of each section gives examples of appropriate entries.

Vent type	Sterilization chamber size (m <sup>3</sup> )	No. of chambers of this size
Sterilization chambers	Example - 30 m <sup>3</sup>	2
	29m <sup>3</sup>	4
	36m <sup>3</sup>	2
	4m <sup>3</sup>	1
	7m <sup>3</sup>	1
CUMULATIVE STERILIZATION CHAMBER SIZE (m <sup>3</sup> ): <u>199m<sup>3</sup></u>		
Vent type	Aeration room or aeration chamber size (m <sup>3</sup> )	No. of rooms or chambers of this size
Aeration rooms or aeration chambers	Example - 280 m <sup>3</sup>	1
	366m <sup>3</sup>	1

<sup>2</sup>Summation of the volume of all sterilization chambers at the facility.

<sup>2</sup>The data a source is required to be in compliance with the Ethylene Oxide Commercial Sterilization and Fumigation NESHAP.

Plant Name: B. Braun Medical, Inc.

5. Complete the following table. If additional space is needed, make copies of this page. The first three rows give examples of appropriate entries.

Vent type (e.g., SCV, ARV, CEV) <sup>a</sup>	Applicable emission limitation <sup>b</sup>
Example - two SCV (30 m <sup>3</sup> )	99% emission reduction
Example - one ARV (280 m <sup>3</sup> )	99% emission reduction
Example - two CEV (30 m <sup>3</sup> )	5,300 ppmv
4 SCV (29m <sup>3</sup> )	99% emission reduction
2 SCV (36m <sup>3</sup> )	99% emission reduction
1 SCV (4m <sup>3</sup> )	99% Emission reduction
1 SCV (7m <sup>3</sup> )	99% emission reduction
1 ARV (366m <sup>3</sup> )	99% emission reduction
4 CEV (29m <sup>3</sup> )	99% emission reduction
2 CEV (36m <sup>3</sup> )	5,300 ppmv
1 CEV (4m <sup>3</sup> )	5,300 ppmv
1 CEV (7m <sup>3</sup> )	5,300 ppmv
	5,300 ppmv

<sup>a</sup>SCV = sterilization chamber vent (includes sterilization chamber vacuum pump); ARV = aeration room vent; CEV = chamber exhaust vent (also referred to as back draft or door hood vent).

<sup>b</sup>Emission limitations could be: 99% emission reduction; 1 ppmv concentration limit or 99% emissions reduction; or 5,300 ppmv concentration limit.

6. Emissions from the sterilization chamber vacuum pump will be controlled as follows (check one):

- ☒ Emissions will be vented to a control device (i.e., control device for the sterilization chamber vent) and will be reduced by 99 percent.
- ☐ A recirculating-fluid vacuum pump will be used.

7. ~~Attach~~ additional pages including any other information required by the State or local agency.

Plant Name: B. Braun Medical, Inc.

8. Print or type the name and title of the Responsible Official for the plant:

<u>Thomas R. Ronca</u>	<u>Senior Vice President of Research &amp; Development</u>
Name	Title

A Responsible Official can be:

- The president, vice-president, secretary, or treasurer of the company that owns the plant;
- The owner of the plant;
- The plant engineer or supervisor; or
- A government official if the plant is owned by the Federal, State, City, or County government.

The Responsible Official must certify below that all of the information presented in this initial report is accurate and true.

I certify the information contained in this report to be accurate and true to the best of my knowledge.

  
\_\_\_\_\_  
Signature of Responsible Official

5/10/96  
\_\_\_\_\_  
Date